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(54) BALLOON DILATION CATHETER

BALLON-DILATATIONSKATHETER

CATHETER DE DILATATION PAR BALLON

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Description

Background of the Invention

The present invention relates generally to the field of catheters. More specifically, the present invention relates to catheters which are adapted to be inserted into the urethral lumen to alleviate obstructive prostatism, a condition quite common in males over the age of 50.

The prostate is a somewhat pear-shaped gland that extends around the urethral lumen from the neck of the bladder to the pelvic floor. Because of the close relationship of the prostate to the urethra, enlargement of the prostate, usually referred to as hypertrophy or hyperplasia, may fairly quickly obstruct the urethra, particularly if the hyperplasia occurs close to the lumen. Such an obstruction inhibits normal micturition, which causes an accumulation of urine in the bladder.

The surgical treatment of hyperplasia of the prostate gland has been a routine procedure in the operating room for many years. One method of surgical treatment is open prostatectomy whereby an incision is made to expose the enlarged prostate gland and remove the hypertrophied tissue under direct vision. Another method of treating obstructive prostatism is a technique known as transurethral resection. In this procedure, an instrument called a resectoscope is placed into the external opening of the urethra and an electrosurgical loop is used to carve away sections of the prostate gland from within the prostatic urethra under endoscopic vision.

The technique of transurethral resection offers many benefits to the patient as compared to open prostatectomy. Using this technique, the trained urologist can remove the hypertrophied prostate with less patient discomfort, a shorter hospital stay and lower rates of mortality and morbidity. Over 333,000 patients underwent this procedure in the United States in 1985, with an average hospital stay of six days. Notwithstanding the significant improvement in patient care resulting from the widespread application of transurethral resection, there remains a need for a less invasive method of treating the symptoms of prostate disease.

One of the earliest methods of relieving acute urinary retention, a symptom associated with prostate disease, was the placement of a catheter through the external urethral opening into the bladder, thereby allowing the outflow of urine from the bladder by way of the catheter lumen. These urinary catheters typically employ a balloon at the tip which, when inflated, prevents the expulsion of the catheter from the body. However, due to problems of infection, interference with sexual activity, and maintenance involved with such catheters, they are generally unacceptable for long term treatment of micturition problems.

U.S. Patent No. 4,432,757 to Davis, Jr. teaches the use of an indwelling urethral catheter assembly, having a Foley-type balloon disposed near the distal end thereof and a substantially non-compliant balloon lead shaft proximate to the Foley-type balloon. The device is adapted to be inserted through the urethra up into the bladder. The Foley-type balloon and the balloon lead shaft are then inflated, although the balloon lead shaft remains relatively non-compliant and therefore does not expand appreciably. Gentle traction is then applied to a catheter sleeve head to sever the sleeve from the remainder of the catheter, leaving the balloon lead shaft in position within the urethra.

Another method of treating hypertrophy of the prostate gland without the need for surgery has been to inject medications into the prostate gland by means of a catheter. Such a device is disclosed in U.S. Patent No. 550,238 to Allen, wherein two balloons are disposed along two sections of a catheter, and inflated to isolate an area within the urethra prior to the injection of the medication. However, these injections are frequently ineffective as the prostate gland exhibits only a limited ability to absorb the injected antibiotics, and proper positioning and retaining of the catheter with respect to the affected area is extremely difficult.

A substantial improvement in an apparatus and corresponding method of treatment for obstructive prostatic hypertrophy is disclosed in Klein, U.S. Patent No. 4,660,560 from which the generic part of claim 1 is derived. In Klein's method, a calibrating catheter is used to measure the distance between the neck of the bladder and the bottom of the prostate gland. A dilation catheter, having an annular balloon with a length equivalent to the measured length, and a Foley-type balloon at the distal end thereof is then inserted into the urethra until the Foley-type balloon is within the bladder. The Foley balloon is then inflated in the bladder and is used to position the dilation balloon in the prostrate. The latter balloon is then inflated, to force the prostate away from the urethral lumen. Use of the Klein catheter can effectively eliminate uncertainty regarding positioning of the upper (distal) end of the dilation balloon, thereby significantly facilitating the treatment of prostatic hypertrophy.

In practicing the Klein method, after the calibration catheter is used to measure the length of the affected prostate, it is withdrawn from the urethra, and the dilation catheter is then inserted. Proper insertion of the dilation catheter is crucial, as stretching of the external urethral sphincter muscle, which lies just below the prostate, could cause incontinence.

Accordingly, in practicing the method of the Klein patent, there is a need for a method and apparatus to permit effective and sure positioning of the proximal end of the dilation balloon with respect to the external urethral sphincter. There is a particular need to permit visualisation of the balloon placement in vivo during the course of the surgical procedure.

Briefly, the present invention provides an intraluminal dilation apparatus according to Claim 1.

Preferably, the dilation catheter is provided with an expandable locating balloon, disposed near the distal tip of the catheter which, when inflated within the bladder,

will provide an anchor with the bladder neck. At least one dilation balloon is preferably provided on the catheter, proximate the locating balloon which, when inflated, conforms to a preselected configuration, so as to radially outwardly dilate the obstruction away from the urethral lumen.

In use, the symptoms of obstructive prostatism are treated by dilation of the prostatic urethra, comprising the steps of inserting the dilation means into the urethra. The location of the dilation means within the urethra is adjusted with respect to an anatomical landmark using non-radiological locating means, i.e. the visible indicator and the dilation means is thereafter expanded so as to radially outwardly dilate the prostatic urethra.

Further objects, features and other advantages of the present invention will become apparent from the ensuing detailed description of preferred embodiments, by way of example only, considered together with the appended drawings.

Figure 1 is a perspective view of a dilation catheter and sheath assembly in accordance with one embodiment of the present invention;
Figure 2 is a partial assembly view of the clipping mechanism;
Figure 3 is a perspective view of a septum, showing an inwardly extending boot sleeve in cut away;
Figure 3a is a perspective view of a second type of septum, having both boot sleeves projecting outwardly;
Figure 4 is an end view of the sheath, showing the unique ellipsoid shape of the inner walls thereof;
Figure 5 is a perspective view of the tip of the sheath, as being deformed by a once-inflated dilation balloon, so as to guide the balloon into the sheath before removal from the urethral lumen;
Figure 6 is a side view of the tip of an obturator;
Figure 7 is a side view of the sheath, having an obturator disposed therein, as ready for insertion into the urethra;
Figure 8 is a cross-sectional view, taken along line 8-8 of Figure 7, showing in more detail the obturator removably disposed therein;
Figure 9 is a cross-sectional view, illustrating a plastic manifold disposed at the proximal end of the dilation catheter during the molding process;
Figure 10 is a cross-sectional view, taken along line 10-10 of Figure 11, showing the lumen arrangement within the catheter shaft;
Figure 11 is a side view of a dilation catheter, having a stylet removably inserted therein;
Figure 12 is a cross-sectional view, taken along line 12-12 of Figure 11, showing the overlap of the shoulder of the locating balloon with the shoulder of the dilation balloon;
Figure 13 is a side view of a dilation balloon, in an inflated state, exhibiting a squared-off configuration at one end, and a tapered configuration at the opposite end thereof, in accordance with one embodiment of the present invention;
Figure 14 is a side view of a dilation balloon, having both ends in a tapered configuration, in accordance with an alternative embodiment of the present invention;
Figure 15 is a side view of a calibration catheter, showing a partial cut away view of an inflation aperture for the expandable balloon;
Figure 16 is a magnified view of the marking disposed near the proximal end of the dilation balloon showing clearance of the external sphincter muscle; and
Figure 17 is a cross-sectional view of the urethral dilation catheter of the present invention operatively inserted within the male urinary tract.
Figure 18 is a perspective view of a dilation catheter having an internal obturator thereon.
Figure 19 is a perspective view of a dilation apparatus having a locking bridge.
Figure 20 is an enlarged perspective view of a locking bridge.

Referring now to the drawings in detail, wherein like reference numerals designate like elements throughout the several views thereof, there is shown generally at 10 in Fig. 1, a dilation catheter and sheath assembly embodying the present invention in a preferred form. The sheath 12 is advantageously a substantially rigid, axially elongate hollow shaft throughout most of its length, but having a flexible distal tip 14. The sheath 12 exhibits an inner surface 16 which is substantially ellipsoid in cross-section, and is adapted to receive and guide an axially elongate catheter 18 and an endoscope 20 longitudinally therethrough. Advantageously, the particular endoscope used is known as a cystoscope.

In one embodiment of the invention, a cylindrical housing 22, disposed near the base of the sheath, exhibits a pair of grooves 24, formed upon two flattened surfaces 26 of the cylindrical housing 22, on opposite sides thereof. An end view of the cylindrical housing 22, as shown in Fig. 4, illustrates the ellipsoid shape of the inner walls 16 of the sheath 12, and the flattened side surfaces 26 thereof. A U-shaped clip 28 is integrally connected to the top of an inflation device 30 and is adapted to removably receive and retain the cylindrical housing 22 so as to enable the device 10 to be operated by one person, without the need for assistance. The removable attachment of the sheath 12 to the U-shaped clip 28 is illustrated in Figure 2. A C-shaped clip 32 may also be provided on the body of the inflation device 30, to removably receive and retain the catheter 18 therein and provide additional support for the proximal end of the device, thus controlling the catheter so it does not interfere with the eyepiece of the endoscope.

Situated on the underside 36 of the cylindrical housing 22 is a drainage port 38, having a cock valve 40 secured therein. The cock valve 40 is adapted to allow back-flowing fluids to escape the sheath 12 when positioned in the "on" position, and to prohibit the release of

such fluids when in the "off" position.

The cylindrical housing 22 includes a hub portion 42, disposed at the proximal end thereof. A rubberized septum 44, preferably formed from a silicon rubber compound, is detachably placed onto the hub 42 of the cylindrical housing 22 so as to provide a seal therefor. As best seen in Figures 3 and 3a, the septum 44 is a circular cap 46, having a pair of boot sleeves 48, 50 integrally connected to the proximal end of the cap 46. In one embodiment, the septum 44 exhibits an outwardly extending boot sleeve 48 an inwardly extending boot sleeve 50. The boot sleeves 48, 50 are adapted to receive the cystoscope lens 20 and the dilation catheter 18, and provide the septum 44 with elasticity at the point of contact therebetween. Without the presence of such sleeves, the rubberized septum 44 would itself deform if a force were applied to either the catheter 18 or cystoscope lens 20, thereby detracting from the septum's sealing ability. Further, the boot sleeves 48, 50 are adapted to readily adjust to and grip the outer diameter of the catheter 18 and lens 20 to yield a good seal therebetween. In an alternative embodiment, as shown in Figure 3a, both of the boot sleeves 52, 54 extend outwardly from the septum cap 44. This embodiment is possible only when there exists sufficient room on the outside of the septum, such that a sharing of a common wall between the two sleeves is not necessitated.

As best seen in Figure 11, the dilation catheter 18 of the present invention comprises an axially elongate catheter shaft 56, having a tapered guiding end 58, and a plurality of parallel conduits disposed therein. Situated near the guiding end 58 of the catheter shaft 56 is a locating balloon 60. The locating balloon 60 is a small latex Foley-type balloon, adapted for inflation by a source of pressurized fluid. Adjacent the locating balloon 60 is a larger dilation balloon 62, having a proximal shoulder 64 and a distal shoulder 66.

A feature of this invention is that the distal shoulder 66 of the dilation balloon 62 is overlapped by a portion of the locating balloon 60, such that, when the balloons are expanded, a minimal valley is left between the two balloons. Both of the balloons 60, 62 are bonded to the outer perimeter of the catheter shaft 56 by suitable adhesive or thermal process. In a similar manner, more than one axially adjacent dilation balloons can be provided on the dilation catheter, each provided with a unique inflation lumen extending through the catheter to a selectively controllable pressure source. The use of two or three or more dilation balloons permits control over the effective length of the dilation region of the catheter, as will be understood by one of skill in the art.

While the overlap of the locating balloon 60 onto the shoulder 66 of the dilation balloon 62 increases the area of dilation by minimizing the distance between the locating balloon 60 and the dilation balloon 62, suboptimal dilation of the affected prostatic urethra 68 still exists due to the tapered nature of expandable balloons, commonly used in dilation processes. To achieve optimal dilation near the ends 70, 72 of the affected prostatic urethra 68, the dilation balloon 62 can be molded with a steep, squared off end 74, as illustrated in Figure 13. Depending on the nature of the affected area of the prostatic urethra 68, it may be desirable to enable urethral dilation very close to the bladder neck 72 or the external sphincter muscle 70. Accordingly, either end of the dilation balloon 62, neither end, or both ends may be provided with a substantially vertical configuration as illustrated in Figures 13, 14 and 17.

A material which is well adapted to construction of the dilation balloon 62 of the present invention is polyethylene terephthalate (PET), such as KODAK's 9921 (TM). Preferably, the balloon 62 is extruded in a straight pipe configuration and then stretched and blown under high temperature and pressure to yield the desired shape 74. This type of technique is commonly applied in the making of angioplasty balloons. It should be noted that the PET material used to construct the dilation balloon exhibits superior tensile strength characteristics to that of materials used in manufacturing other types of dilation balloons, for example older angioplasty balloons. The PET material used to construct the dilation balloon of the present invention has a tensile strength of between 1.4×10^8 and 3.5×10^8 Nm^{-2} (20,000 and 50,000 psi), and is rated to withstand at least 3 bar (atmospheres) of pressure, and as much as 5 bar (atm).

If a rubberized latex material were used to fabricate the dilation balloon of the present invention, the walls of the balloon would necessarily be much thicker in order to withstand the exceedingly high pressures required for adequate dilation of the affected prostatic urethra. Thus, the PET material, by virtue of its superior strength, allows a thinner balloon to be utilized. The thinness of the balloon thus formed, makes possible a dilation balloon 62 which, in an uninflated state, conforms to the external walls of the catheter shaft 56, thereby providing a dilation catheter 18 having substantially the same size and shape as the unstretched lumen. However, the increased strength of the material also dictates a balloon which is somewhat stiff and substantially less pliable than a latex balloon.

Consequently, when negative pressure is applied to collapse the dilation balloon 62 made of the PET material, sharp ridges may form on the exterior surface thereof. Advantageously, the distal tip 14 of the introduction sheath 12 is formed of a flexible material, which readily deforms to the gross contours of the deflated dilation balloon 62, so as to coerce the balloon 62 into the introduction sheath 12 prior to the withdrawal of the catheter 18 from the urethra. Preferably, the tip 14 is formed from a substantially malleable Poly Vinyl Chloride (PVC) compound, which is RF welded to rigid shaft portion 12 of the sheath.

To ensure that the catheter 18 is fully within the introduction sheath 12 prior to the withdrawal thereof a second, visible indicator, such as the marking 78 on the exterior shaft 56 of the catheter 18 is provided. As the catheter shaft 56 and deflated dilation balloon 62 are gradually withdrawn from the urethra, the marking 78

will be advanced out of the sheath 12. When the designated marking 78 becomes visible, the catheter 18 is fully retracted within the sheath 12, and the device 10 may be withdrawn, without causing undue trauma to the urethral lumen.

As best seen in cross-section in Figure 10, the catheter shaft 56 houses a pair of circular inflation conduits 80, 82 and an irrigation conduit 84. The inflation conduit 80 having an aperture 86 underlying the locating balloon 60 exhibits a tubular passageway which permits pressurized fluid to be transmitted into the chamber enclosed by the locating balloon 60 , so as to selectively inflate the balloon 60 to a suitable level. Likewise, the inflation conduit 82 having a pair of inflation apertures 90, 92 underlying the dilation balloon 62 allows pressurized fluid to selectively fill the balloon 62 to a desired level.

To facilitate inflation of the locating balloon 60, a simple fluid valve 94 may be connected to the proximal end of the conduit 80. This valve 94 is integrally connected to the inflation conduit 80 and may be easily manipulated to allow quick sealing of the conduit 80 and maintain the pressurized fluid within the balloon chamber 60 and the conduit 80. The locating balloon 60 may be pressurized by inserting a hypodermic syringe (not shown) into the valve 94, with the valve 94 in its open condition. By forcing fluid into the conduit 80, the locating balloon 60, at the distal end of the inflation conduit will be inflated. The valve 94 may then be closed, and the hypodermic syringe removed, leaving the locating balloon 60 in an inflated state.

Since inflation of the dilation balloon 62 is more critical, the source of pressurized fluid 98 used to inflate the dilation balloon 62 is connected to a pressure gauge 100. Preferably, the inflation device 98 includes a syringe barrel 102 having a threaded rod and ratchet mechanism 104 which replaces the conventional plunger. This configuration allows fine tuning of the pressure amassed within the dilation balloon 62 by screw turning the threaded rod 104. It has been determined that an intra-balloon pressure of approximately 3 bar (atm.) (or 45 p.s.i.g.)is sufficient to force the prostate away from the urethral lumen to relieve the obstruction and reestablish normal micturition.

As a further alternative, the dilation catheter of the present invention can be configured to carry an expandable implantable stent over the dilation region thereof. This embodiment of the present invention would permit both expansion of the urethra and leaving behind of an expanded intraluminal support to ensure long-term patency of the urethra. The use of such implantable stents is disclosed in detail in U.S. Patent No. 4,762,128 issued to Robert F. Rosenbluth on August 9, 1988.

The catheter comprises a radially expandable region near the distal end thereof which, in its unexpanded state, has an outer diameter that is preferably slightly smaller than the outer diameter of the adjacent region of the catheter. Thus, the collapsed expandable region forms the bottom of an annular depression about the catheter.

The stent is removably, coaxially disposed about the expandable region of the catheter and within the annular depression formed therearound, and is controllably radially outwardly expandable in response to pressure from the expandable region of the catheter. When the stent is coaxially disposed about the expandable region of the catheter, and in an unexpanded state, the outer diameter of the unexpanded stent is approximately the same as or less than the outer diameter of the adjacent region of the catheter. Preferably, the distal end of the catheter comprises a flexible, resilient material in a shape to facilitate insertion into and negotiation of a collapsed lumen with minimal trauma to the lining thereof. Alternatively, for use with an introduction sheath, the stent may extend radially outwardly of the adjacent catheter shaft in the unexpanded state.

The radially outwardly expandable tubular stent for restoring patency to a collapsed portion of the urethral lumen comprises a material that is compatible with the urethral environment, and is capable of remaining in its expanded state following removal of the expansion catheter described above, thereby holding open the lumen of the urethra against a restricting pressure, such as that exerted by a hypertrophied prostate gland. The cross section of the expanded stent may be circular, or may also be a non-circular configuration which more closely corresponds to the shape of the normal lumen within the urethra. One embodiment of the stent in its expanded state comprises a substantially uniform cross-sectional area throughout its axial length. In another embodiment, the stent comprises a smaller cross-sectional area at its axial ends than in the central region thereof. In addition, the axial end regions of the stent may comprise a flexible material, or may taper in a radial inward direction thereby easing the transition from the lumen of the stent to the lumen of the urethra.

Referring to Figures 11 and 16, near the proximal end of the dilation balloon 62, and encircling the proximal shoulder 64 thereof, is a heavy black line 106 for use with the cystoscope embodiment of the present invention. Prior to inflating the dilation balloon 62, care should be taken to ensure that the black line 106 does not extend onto any portion of the external urethral sphincter muscle 108. This is vitally important as accidental dilation of the sphincter 108 may cause the patient to lose voluntary control over micturition, especially if the sphincter experiences plastic deformation, i.e., the inability to return to its original shape.

A further feature of this invention is the provision of an irrigation system. As described below, the system provides the dual features of both flushing blood away from the lens of the cystoscope to aid in the viewing of the external sphincter muscle and the black line 106 on the shoulder 64 of the dilation balloon 62 and inhibiting coagulation of blood within the urethra. This flushing system includes a plurality of irrigation ports 110 disposed along the exterior shaft 56 of the catheter 18, proximate to the line 106 are provided. The irrigation

ports 110 are adapted to continuously flush fluid, for example, saline, from the irrigation conduit 84, which extends through the center of the catheter shaft 56. The irrigation conduit 84 is provided with a coupling device 112 at the proximal end thereof, adapted to receive a source of flushing fluid, which, for example, can be a hanging container of saline (not shown), having a length of flexible tubing extending therefrom, for connection to the coupling device 112. The source of fluid is elevated and allowed to flow by gravity through the irrigation conduit 84 and out the irrigation ports 110, so as to flush blood away from the lens 20 and allow the urologist an unobstructed view of the external sphincter muscle 108 and the line 106 encircling the proximal shoulder 64 of the dilation balloon 62.

In addition to permitting an unobstructed view of the proximal shoulder 64 of the balloon 62, the flushing of blood inhibits coagulation, and therefore substantially eliminates clotting within the urethral lumen. Back-flowing flushing fluid and blood is drained from the urethra through introduction sheath 12 by gravity flow. A drainage reservoir (not shown) is connected to the cock valve 40 which, when in its open position, allows the back-flowing fluids to drain, by gravity flow, into the reservoir and subsequently disposed of. Alternatively, the flushing fluid can be supplied through the sheath 12 to flush blood away from the cystoscope lens 20. In this embodiment, the irrigation ports 110 of the irrigation conduit 84 function as influent ports to drain the flushing fluid and blood out of the urethra.

Located at the proximal end of the catheter shaft 56, and integrally connected thereto, is a Y-shaped plastic manifold 118. The manifold 118 is adapted to define and separate the trio of conduits 80, 82, 84 disposed within the body of the catheter shaft 56. Preferably, the manifold 118 is preformed in the Y-shaped configuration and is adapted to connect to the catheter shaft 56 and trio of conduits at the proximal end thereof. The catheter shaft 56 should be bent and cut to expose the inflation conduits 80, 82 respectively. The irrigation conduit 84 need not be exposed in this manner, as the manifold 118 includes a substantially straight portion in which the proximal end of the irrigation conduit 84 will reside. As shown in Figure 9, during the molding process flexible core pins 122, 124 are inserted into the exposed inflation conduits 80, 82 to respectively maintain the openings into the inflation conduits and provide support therefor during the molding process. In a similar manner, a straight core pin 126 is inserted into the irrigation conduit 84, and the catheter 18 is set into the preformed plastic manifold 118. Plastic is then injected into the manifold 118 to form a tight seal, and the core pins 122, 124, 126 are removed after the plastic has hardened.

In accordance with a further embodiment of the present invention, a source of pulsatile pressure (not illustrated) is provided for inflating the dilation balloon. Pumps capable of generating a variable frequency pulsatile pressure are well known in the art, and can readily be constructed by a cam-driven piston pump, as will be appreciated by one of skill in the art. By introducing and withdrawing fluid through the dilation port of the catheter, the balloon can be made to pulse at a desired frequency. Preferably, a pulsatile pressure source is connected to the dilation balloon which is capable of vibration at about the natural body frequency of approximately 8 Hz. High frequency pulsation of the balloon can be accomplished by providing an acoustic transducer on the dilation catheter, such as within the dilation balloon, and driven by an external variable frequency source of acoustic vibration. However, lower or higher frequencies such as from 1/60 Hz to as high as 5000 Hz may also facilitate reduction of the symptoms of obstructive prosthetism.

In accordance with a further embodiment of the dilation catheter of the present invention, illustrated in Figure 18, there is provided a dilation catheter 170, having a dilation balloon 172, or other dilation means thereon, which is provided at its distal end 174 with an integrally moulded, or otherwise secured, obturator 176 for facilitating introduction of the dilation catheter within the urethra. The obturator 176 may be moulded or formed from any of a variety of materials which are substantially biologically inert in the urethral environment, and which facilitate secure bonding to the material of the dilation catheter shaft 170 so that the obturator 176 will not become detached from the shaft in use. For example, a polyvinylchloride (PVC) obturator may be securely bonded to a PVC catheter shaft.

The dilation catheter 170 having an integral obturator 176 thereon is used together with an introduction sheath 178. For this purpose, the proximal end 180 of the integral obturator 176 is tapered slightly as illustrated in Figure 19, so that it may be snugly fitted within the distal end of the introduction sheath 178.

An integral obturator 176 can also be configured like the obturator 148 in Figure 7 and 8, with a more gradual taper to co-operate with flexible tip 14 of sheath 12. In addition, as with the flexible distal tip 14 illustrated in Figure 5, sheath 178 can be further provided with a flexible region 179 for receiving proximal end 180 when the catheter is in the retracted position.

Following introduction of the sheath 178 in accordance with the present embodiment of the invention, the dilation catheter 170 and integral obturator 176 may be extended distally relative to sheath 178 to expose the dilation means 172. The dilation means is then positioned in accordance with any of the positioning techniques described herein, and dilation is accomplished. Following dilation, the dilation means is reduced in external diameter, and the dilation catheter is retracted axially into the sheath so that the proximal end 180 of the obturator 176 fits snugly within the distal end of the sheath 178.

Referring to Figures 19 and 20, there is illustrated a locking bridge 186 for facilitating control over the various components of the dilation assembly, according to one embodiment of the present invention. Dilation catheter 182 is illustrated as extending through a dilation assem-

bly housing 184 in a manner similar to that discussed in connection with Figure 1. Dilation catheter 182 is additionally illustrated as extending through a tubular channel 183 contained in locking bridge 186, enabling a variety of securing functions as will be discussed.

A first locking means 188, such as a thumb screw 190, is provided on the locking bridge 186, for securing the locking bridge 186 with respect to the dilation catheter 182. Although illustrated as a thumb screw 190, the first securing means 188 may comprise any of a variety of means well known to one of skill in the art which may be adapted for securing locking bridge 186 against axial movement along dilation catheter 182.

Locking bridge 186 is further provided with a second tubular channel 192 for receiving a standard cystoscope therethrough. Channel 192 is provided with a second securing means 194 for securing the endoscope with respect to locking bridge 186. As discussed in connection with first securing means 188, the second securing means 194 can be any of a variety of means known in the art for securing a tubular member against axial motion through the locking bridge 186.

For example, referring to Figure 20, the second securing means 194 can comprise a rotatable sleeve 196 having a lever 198 thereon to facilitate rotation. The sleeve 196 is threadedly engaged with the body of locking bridge 186, and rotation of sleeve 196 provides a compressive retention force on an elongate body extending through channel 192, such as by compression of an annular ring of elastomeric material, or radial inward movement of a multiple jaw chuck, as are well known in the art. Locking bridge 186 is preferably additionally provided with a further securing means (not illustrated) for securing locking bridge 186 to the dilation assembly housing 184. This further securing means may comprise any of a variety of securing means, as will be appreciated by one of skill in the art.

The foregoing structures enable the clinician to fix the axial position of the dilating means in relation to the sheath, to fix the position of the locating means with respect to the sheath and to alternatively fix the position of the locating means with respect to the dilating means.

Method of Using the Dilation Catheter

Prior to dilating the obstructed urethral lumen, the length of the affected prostatic urethra 68 should be measured. This may be accomplished by the use of a calibration catheter 128, as illustrated in Figure 15. The calibration catheter 128 is an axially elongate shaft 130, having an expandable balloon 132 located near the distal end 134 thereof, and an inflation conduit (not shown) which extends substantially the entire length of the shaft 130. The expandable balloon 132 is adapted to be inflated through an inflation aperture 136, extending from the inflation conduit by a source of pressurized fluid (not shown). A plurality of graduated markings 138 extend along the exterior shaft 130 of the catheter 128, commencing near the proximal end 140 of the expandable balloon 132, and are adapted to be read from the distal end 134 of the catheter 128 to the proximal end 142.

The calibration catheter 128 is adapted to be received into the sheath of a standard cystoscope, and the cystoscope inserted into the urethra through the penile meatus. Once the distal end 134 and expandable balloon 132 of the calibration catheter 128 enters the bladder 144, the expandable balloon 132 may be inflated, and the catheter 128 slowly withdrawn from the urethra until the balloon 132 becomes lodged within the bladder neck 72. Graduated markings 138, inscribed on the exterior shaft 130 of the catheter 128 can be used to measure the distance between the bladder neck 72 and the lower end 70 of the affected prostatic urethra 68. Once such a measurement has been determined, the expandable balloon 138 may be deflated, and the catheter 128 withdrawn.

An introduction sheath 12, as illustrated in Figures 7 and 8 is then readied for insertion through the external urethral opening. An obturator 146, as shown in Figures 6, 7 and 8, having a smooth, tapered end 148 with no sharp edges is inserted into the sheath 12, and secured to the hub 42 of the cylindrical housing 22 by chamfered clips 150. The flexible tip 14 of the sheath 12 tapers inwardly, so as to grip the extending portion of the obturator 146 and provide a fairly smooth surface continuation of the introduction sheath. This mild transition between the obturator 146 and sheath 12 is instrumental in reducing damage and trauma to the tender urethral lumen. Once the sheath 12 has been fully inserted within the urethral lumen, the chamfered clips 150 may be released, and the obturator 146 withdrawn.

A catheter shaft 56, having a dilation balloon 62 with a length approximately equivalent to that measured by the calibration catheter 128, is then inserted through one 48 of two boot sleeves of the septum 44, until at least that portion of the catheter shaft 56 to which the expandible balloons 60, 62 are attached extends therethrough. The septum 44 is then friction fit onto the hub 42 of the cylindrical housing 22 such that the catheter 18 is in alignment with the larger diameter ellipsoid section 152 of the sheath 12. The cystoscope lens 20 is then inserted into the other boot sleeve 50, and is then urged through the sheath 12 and into the urethra after placement of the catheter 18.

To provide support for the catheter 18, an elongate stylet 154 may be inserted into the irrigation conduit 84, as illustrated in Figure 11. The stylet 154 facilitates the ease with which the catheter 18 may be inserted into the urethra, and may remain within the irrigation conduit 84 until the locating balloon 60 is disposed within the bladder 144, at which time the stylet 154 should be removed. Once the locating balloon 60 is within the bladder 144, the inflation conduit 80 may be coupled to a source of pressurized fluid so as to inflate the locating balloon 60. The catheter 18 is then gradually withdrawn from the bladder 144 until the balloon 60 is lodged within the bladder neck 72. When the locating balloon

60 is properly positioned within the neck 72 of the bladder 144, a seal is formed therebetween which prohibits fluids accumulating within the bladder 144 from travelling down the urethra and also prohibits fluids from flowing into and filling up the bladder from the urethra.

Once the catheter 18 has been properly situated with respect to the upper end 72 of the affected prostatic urethra 68, the irrigation conduit 84 may be connected to a source of flushing fluid. The flushing fluid is gravity fed through the irrigation conduit 84 and out the irrigation ports 110, so as to wash existent blood away from the cystoscope lens 20 and provide the urologist with an unobstructed view of the proximal shoulder 64 of the dilation balloon 62, and adjacent organs. Looking through the cystoscope, the urologist can manipulate the catheter 18 to confirm that the dilation balloon 62 is clear of the external urethral sphincter muscle 108, so as to ensure that the sphincter 108 will not inadvertently be dilated.

Upon properly positioning the dilation balloon 62 with respect to both the bladder neck 72 and the sphincter 108, the inflation conduit 82 for the dilation balloon 62 may be connected to a source of pressurized fluid 98. As described above, the inflation source 98 should enable a accurate, progressive dilation under constant control of the pressure being applied within the dilation balloon 62. The device remains within the affected prostatic urethra 68, until sufficient pressure dilation has been achieved. Subsequent to attaining adequate pressure dilation of the prostatic urethra, and eliminating the urinary outflow obstruction, the balloons 60, 62 may be deflated, releasing the pressurized fluid therefrom.

As the dilation balloon 62 is deflated, sharp ridges may form on the outer surface thereof, due to the stiffness of the material from which it was formed. As shown in Figure 5, the flexible tip 14 of the introduction sheath 12 readily deforms and flares, so as to coerce the dilation balloon 62 back into the sheath 12. When the marking 78, indicative of the time at which the dilation balloon 62 is completely within the sheath 12 becomes visible, the device may be withdrawn from the urethra.

In view of the medical treatment to be administered in using the device of the present invention, it is necessary that the device be aseptically clean. Accordingly, the dilation catheter and sheath can be cleansed and sterilized readily and easily either prior to use thereof, or packaged in this condition, available for immediate use. Further, both the catheter and sheath may be discarded after use, negating the need for recleaning and resterilization.

It will be appreciated that certain structural variations may suggest themselves to those skilled in the art. The foregoing detailed description is to be clearly understood as given by way of illustration only.

For example, the black line 106 as a visible indicator could be replaced by a radial enlargement of the dilation catheter, and this radial enlargement could comprise a radially outwardly extending annular ridge on the surface of the dilation catheter.

Claims

1. An intraluminal dilation apparatus (10) for relieving flow obstructions within the urethra comprising an axially elongate introduction sheath (12, 178), adapted for insertion into the urethra, a cystoscope (20), an axially elongate dilation catheter (18, 170), having a shaft (56), a distal end (58, 174) and at least one dilation means (62, 172) secured thereto, wherein said axially elongate dilation catheter (18, 170) extends through and is axially movable within said axially elongate introduction sheath (12, 178), to permit positioning of said dilation means (62, 172) within the urethra, characterised by:

   a peripheral line or a radial enlargement is positioned as a visible indicator (106) on said axially elongate dilation catheter (18, 170) near the proximal end of the dilation means (62, 172) such that said visible indicator (106) can be seen through said cystoscope (20) and the position of the visible indicator (106) provides an indication of the position of said dilation means (62,172) relative to an anatomical landmark.

2. An intraluminal dilation apparatus (10) as in Claim 1, having the said radial enlargement which comprises a radially outwardly extending annular ridge.

3. An intraluminal dilation apparatus (10) as in Claim 1, further comprising a locking bridge (186) having a first securing means (188) on the locking bridge (186) for fixing the position of the dilation means (62, 172) relative to the locking bridge (186).

4. An intraluminal dilation apparatus (10) as in Claim 3, further comprising a second securing means (194) on the locking bridge (186) for fixing the position of the cystoscope relative to the locking bridge (186).

5. An intraluminal dilation apparatus (10) as in Claim 1, further comprising an obturator (146, 148, 176) for facilitating introduction of the dilation means (172) into the urethra.

6. An intraluminal dilation apparatus (10) as in Claim 5, wherein said obturator (176) is integral with said axially elongate dilation catheter (18, 170) at said distal end (58, 174).

7. An intraluminal dilation apparatus (10) as in Claim 5, wherein said obturator (146, 148) is tapered for fitting within said distal end of said axially elongate introduction sheath (12, 178).

8. An intraluminal dilation apparatus (10) as in Claim 1, wherein said axially elongate introduction sheath (12, 178) further comprises a flexible distal tip (14, 179).

9. An intraluminal dilation apparatus (10) as in Claim 8, wherein said flexible distal tip (14, 179) readily deforms the contours of said dilation means (62, 172) when said dilation means (62, 172) is not dilated.

10. An intraluminal dilation apparatus (10) as in Claim 1, wherein said axially elongate introduction sheath (12) has an inner surface (16) which is substantially ellipsoid in cross-section and is adapted to receive and guide said axially elongate dilation catheter (18, 170) and said cystoscope (20).

11. An intraluminal dilation apparatus (10) as in Claim 1, further comprising an inflatable locating balloon (60) distally located on said axially elongate dilation catheter (18, 170).

12. An intraluminal dilation apparatus (10) as in Claim 11, wherein said dilation means (62, 172), further comprises a distal shoulder or end (66, 74), and wherein said locating balloon (60) overlaps a portion of said distal shoulder (66, 74).

13. An intraluminal dilation apparatus (10) as in Claim 1, wherein said dilation means (62, 172) further comprises a proximal shoulder or end (64) and a distal shoulder or end (66, 74), and wherein either or both of said proximal shoulder (64) and said distal shoulder (66, 74) are squared off.

14. An intraluminal dilation apparatus (10) as in Claim 1, wherein said axially elongate dilation catheter (18, 170) has an irrigation conduit (84) and at least one irrigation port (110) proximate to the visible indicator (106).

15. An intraluminal dilation apparatus (10) as in Claim 1, wherein said axially elongate dilation catheter (18, 170) has a second visible indicator (78) that becomes visible to the operator during withdrawal of said axially elongate dilation catheter (18, 170) when said dilation means (62, 172) is fully retracted within said axially elongate introduction sheath (12, 178).

16. An intraluminal dilation apparatus (10) as in Claim 15, wherein the second visible indicator (78) comprises a line.

17. An intraluminal dilation apparatus (10) as in Claim 1, wherein said axially elongate dilation catheter (18, 170) further comprises an expandable implantable stent over said dilation means (62, 172).

18. An intraluminal dilation apparatus (10) as in Claim 17, wherein said expandable implantable stent has an outer diameter that is equal to or smaller than an outer diameter of said axially elongate dilation catheter (18, 170) adjacent to said stent, when said stent is in an unexpanded state.

19. An intraluminal dilation apparatus (10) as in Claim 1, wherein said dilation means (62, 172) is dilated by a pulsatile pressure source.

Patentansprüche

1. Intraluminale Dilatationsvorrichtung (10) zum Beseitigen von Flußbehinderungen in der Harnröhre mit einer axialen, länglichen Einführungshülse (12, 178), die zur Einführung in die Harnröhre geeignet ist, einem Zystoskop (20), einem axialen, länglichen Dilatationskatheter (18, 170) mit einem Schaft (56), einem körperfernen Ende (58, 174) und wenigstens einer Dilatationseinrichtung (62, 172), die an ihm befestigt ist, wobei der axiale längliche Dilatationskatheter (18, 170) sich durch die axiale längliche Einführungshülse (12, 178) hindurcherstreckt und in dieser axial beweglich ist, um die Positionierung der Dilatationseinrichtung (62, 172) in der Harnröhre zu ermöglichen, dadurch gekennzeichnet, daß eine periphere Linie oder eine radiale Vergrößerung als ein sichtbarer Indikator (106) an dem axialen, länglichen Dilatationskatheter (18, 170) in der Nähe des körpernahen Endes der Dilatationseinrichtung (62, 172) positioniert ist, so daß der sichtbare Indikator (106) durch das Zystoskop (20) gesehen werden kann und die Position des sichtbaren Indikators (106) eine Anzeige der Position der Dilatationseinrichtung (62, 172) relativ zu einer anatomischen Kennungsmarke bildet.

2. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, wobei die radiale Vergrößerung vorgesehen ist und eine sich radial nach außen erstreckende ringförmige Rippe umfaßt.

3. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, wobei ferner eine Sperrbrücke (186) mit einer ersten Befestigungseinrichtung (188) an der Sperrbrücke (186) zur Festlegung der Position der Dilatationseinrichtung (62, 172) relativ zu der Sperrbrücke (186) vorgesehen ist.

4. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 3, wobei ferner eine zweite Befestigungseinrichtung (194) an der Sperrbrücke (186) zur Festlegung der Position des Zystoskops relativ zu der Sperrbrücke (186) vorgesehen ist.

5. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, wobei ferner ein Obturator (146, 148, 176) zur Erleichterung der Einführung der Dilatationseinrichtung (172) in die Harnröhre vorgesehen ist.

6. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 5, wobei der Obturator (176) einstückig mit dem axialen länglichen Dilatationskatheter (18, 170) an dem körperfernen Ende (58, 178) ausgebildet ist.

7. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 5, wobei der Obturator (146, 148) sich zum Einsetzen in das körperferne Ende der axialen länglichen Einführungshülse (12, 178) verjüngt.

8. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, wobei die axiale längliche Einführungshulse (12, 178) ferner eine flexible körperferne Spitze (14, 179) aufweist.

9. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 8, wobei die flexible körperferne Spitze (14, 179) die Konturen der Dilatationseinrichtung (62, 172) leicht deformiert, wenn die Dilatationseinrichtung (62, 172) nicht vergrößert ist.

10. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, wobei die axiale längliche Einführungshülse (12) eine Innenfläche (16) aufweist, die einen im wesentlichen ellipsoidischen Querschnitt besitzt und den axialen länglichen Dilatationskatheter (18, 170) und das Zystoskop (20) aufnehmen und führen kann.

11. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, die ferner einen aufblasbaren Lokalisierungsballon (60) aufweist, der körperfern an dem axialen länglichen Dilatationskatheter (18, 170) angeordnet ist.

12. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 11, wobei die Dilatationseinrichtung (62, 172) ferner eine körperferne Schulter oder ein körperfernes Ende (66, 74) aufweist und wobei der Lokalisierungsballon (60) einen Bereich der körperfernen Schulter (66, 74) überlappt.

13. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, wobei die Dilatationseinrichtung (62, 172) ferner eine körpernahe Schulter oder ein körpernahes Ende (64) und eine körperferne Schulter oder ein körperfernes Ende (66, 74) aufweist und wobei entweder die körpernahe Schulter (64) und die körperferne Schulter (66, 74) oder die körpernahe Schulter (64) oder die körperferne Schulter (66, 74) rechteckig ausgestellt sind.

14. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, wobei der axiale längliche Dilatationskatheter (18, 170) eine Spühlleitung (84) und wenigstens eine Spühlöffnung (110) nahe am sichtbaren Indikator (106) aufweist.

15. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, wobei der axiale längliche Dilatationskatheter (18, 170) einen zweiten sichtbaren Indikator (78) aufweist, der für den Operateur während des Zurückziehens des axialen länglichen Dilatationskatheters (18, 170) sichtbar wird, wenn die Dilatationseinrichtung (62, 172) vollständig in die axiale längliche Einführungshülse (12, 178) zurückgezogen ist.

16. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 15, wobei der zweite sichtbare Indikator (78) eine Linie umfaßt.

17. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, wobei der axiale längliche Dilatationskatheter (18, 170) ferner über der Dilatationseinrichtung (62, 172) eine expandierbare implantierbare Aufspannungseinrichtung aufweist.

18. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 17, bei der die expandierbare implantierbare Aufspanneinrichtung einen Außendurchmesser besitzt, der gleich oder kleiner als der Außendurchmesser des axialen länglichen Dilatationskatheters (18, 170) in der Nähe der Aufspanneinrichtung ist, wenn die Aufspanneinrichtung nicht expandiert ist.

19. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, wobei die Dilatationseinrichtung (62, 172) durch eine pulsierende Druckquelle vergrößert wird.

Revendications

1. Appareil de dilatation intraluminale (10) pour réduire les obstructions à la circulation à l'intérieur de l'urètre, comprenant une gaine d'introduction (12, 178) à élongation axiale, adaptée pour l'insertion dans l'urètre, un cystoscope (20), un cathéter de dilatation (18, 170) à élongation axiale ayant un axe (56), une extrémité distale (58, 174) et au moins un moyen de dilatation (62, 172) qui lui est fixé, dans lequel ledit cathéter de dilatation (18, 170) à élongation axiale s'étend à travers et est mobile axialement à l'intérieur de ladite gaine d'introduction (12, 178) à élongation axiale, pour permettre le positionnement dudit moyen de dilatation (62, 172) à l'intérieur de l'urètre, caractérisé en ce que :

une ligne périphérique ou un élargissement radial est positionné comme indicateur visible (106) sur ledit cathéter de dilatation (18, 170) à élongation axiale, près de l'extrémité proximale du moyen de dilatation (62, 172) de telle façon que ledit indicateur visible (106) puisse être vu à travers ledit cystoscope (20) et la position de l'indicateur visible (106) fournit une indication de la position dudit

moyen de dilatation (62, 172) par rapport à un point de repère anatomique.

2. Appareil de dilatation intraluminale (10) selon la revendication 1, ayant ledit élargissement radial qui comprend un bord annulaire s'étendant dans le sens radial, vers l'extérieur.

3. Appareil de dilatation intraluminale (10) selon la revendication 1, comprenant en outre un pont de blocage (186) ayant un premier moyen de sécurité (188) pour fixer la position du moyen de dilatation (62, 172) par rapport au pont de blocage (186).

4. Appareil de dilatation intraluminale (10) selon la revendication 3, comprenant en outre un deuxième moyen de sécurité (194) sur le pont de blocage (186) pour fixer la position du cystoscope par rapport au pont de blocage (186).

5. Appareil de dilatation intraluminale (10) selon la revendication 1, comprenant en outre un obturateur (146, 148, 176) pour faciliter l'introduction du moyen de dilatation (172) dans l'urètre.

6. Appareil de dilatation intraluminale (10) selon la revendication 5, dans lequel ledit obturateur (176) est solidaire avec ledit cathéter de dilatation (18, 170) à élongation axiale et ladite extrémité distale (58, 174).

7. Appareil de dilatation intraluminale (10) selon la revendication 5, dans lequel ledit obturateur (146, 148) est taillé en cône pour s'adapter à l'intérieur de ladite extrémité distale de ladite gaine d'introduction (12, 178) à élongation axiale.

8. Appareil de dilatation intraluminale (10) selon la revendication 1, dans lequel ladite gaine d'introduction (12, 178) à élongation axiale comprend en outre une extrémité distale flexible (14, 179).

9. Appareil de dilatation intraluminale (10) selon la revendication 8, dans lequel ladite extrémité distale flexible (14, 179) déforme facilement les contours dudit moyen de dilatation (62, 172) lorsque ledit moyen de dilatation (62, 172) n'est pas dilaté.

10. Appareil de dilatation intraluminale (10) selon la revendication 1, dans lequel ladite gaine d'introduction (12) à élongation axiale comporte une surface intérieure (16) qui a une section ellipsoïdale, et qui est adaptée pour recevoir et guider ledit cathéter de dilatation (18, 170) à élongation axiale et ledit cystoscope (20).

11. Appareil de dilatation intraluminale (10) selon la revendication 1, comprenant un ballon de localisation (60) gonflable placé de manière distale sur ledit cathéter de dilatation (18, 170) à élongation axiale.

12. Appareil de dilatation intraluminale (10) selon la revendication 11, dans lequel ledit moyen de dilatation (62, 172) comprend en outre un épaulement ou une extrémité distale (66, 74) et dans lequel ledit ballon de positionnement (60) recouvre une partie dudit épaulement distal (66, 74).

13. Appareil de dilatation intraluminale (10) selon la revendication 1, dans lequel ledit moyen de dilatation (62, 172) comprend en outre un épaulement ou une extrémité (64) proximale et un épaulement ou une extrémité distale (66, 74) et dans lequel l'un ou l'autre, ou les deux épaulements proximaux (64) et ledit épaulement distal (66, 74) sont placés en équerre.

14. Appareil de dilatation intraluminale (10) selon la revendication 1, dans lequel ledit cathéter de dilatation (18, 170) à élongation axiale comporte un conduit d'irrigation (84) et au moins un port d'irrigation (110) proches de l'indicateur visible (106).

15. Appareil de dilatation intraluminale (10) selon la revendication 1, dans lequel ledit cathéter de dilatation (18, 170) à élongation axiale comporte d'un deuxième indicateur visible (78) qui devient visible pour l'opérateur pendant le retrait dudit cathéter de dilatation (18, 170) à élongation axiale quand ledit moyen de dilatation (62, 172) est totalement rétracté à l'intérieur de ladite gaine d'introduction (12, 178) à élongation axiale.

16. Appareil de dilatation intraluminale (10) selon la revendication 15, dans lequel ledit deuxième indicateur visible (78) comprend une ligne.

17. Appareil de dilatation intraluminale (10) selon la revendication 1, dans lequel ledit cathéter de dilatation (18, 170) à élongation axiale comporte en outre un stent implantable et extensible au-dessus dudit moyen de dilatation (62, 172).

18. Appareil de dilatation intraluminale (10) selon la revendication 17, dans lequel ledit stent implantable et extensible a un diamètre extérieur égal ou plus petit qu'un diamètre extérieur dudit cathéter de dilatation (18, 170) à élongation axiale adjacent audit stent, quand ledit stent est dans un état non dilaté.

19. Appareil de dilatation intraluminale (10) selon la revendication 1, dans lequel ledit moyen de dilatation (62, 172) est dilaté par une source de pression à pulsations.

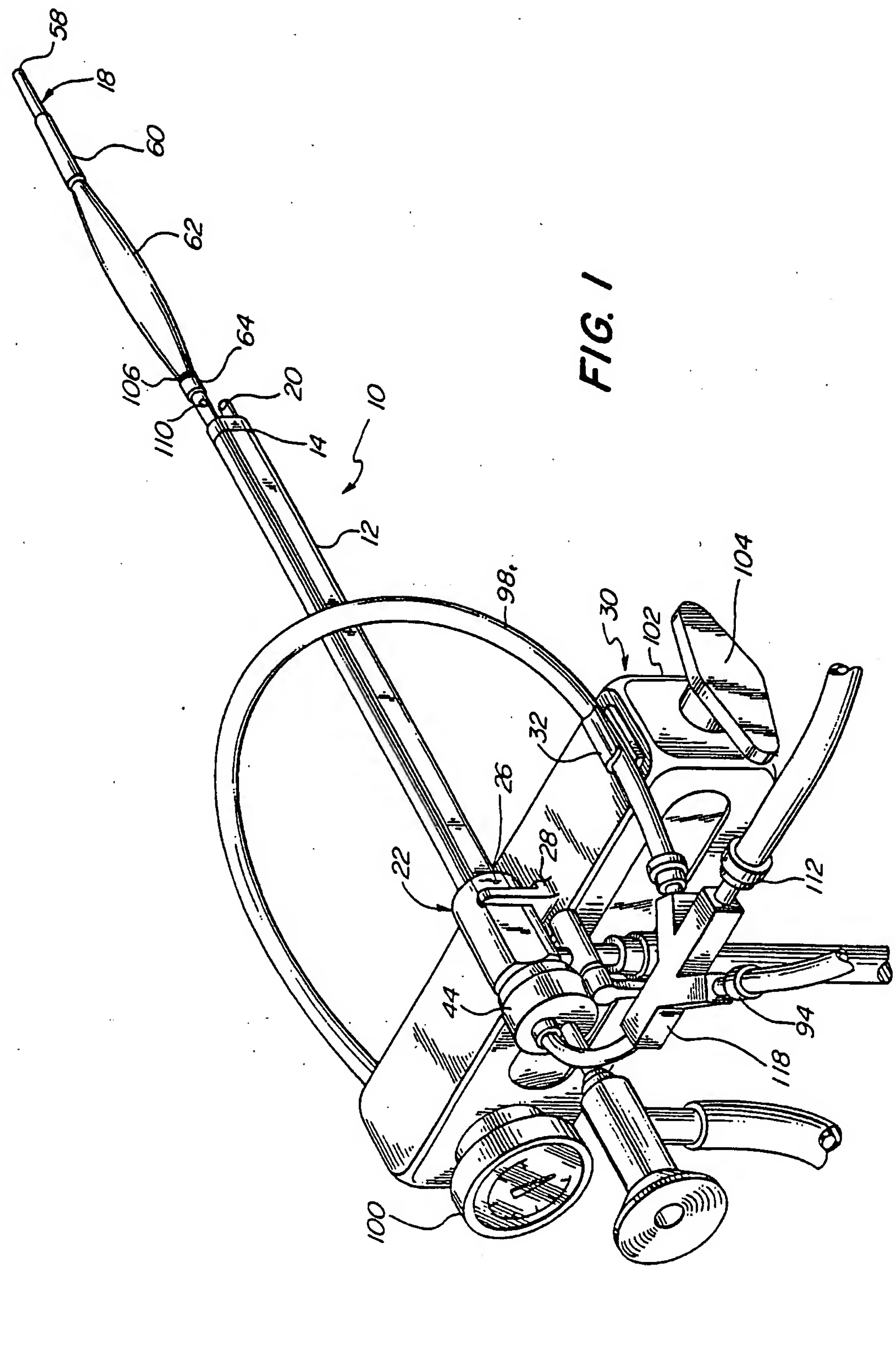

58
18
60
62
64
106
20
10
110
14
12
98
104
30
102
32
26
28
22
112
44
94
118
100

FIG. 1

FIG. 2

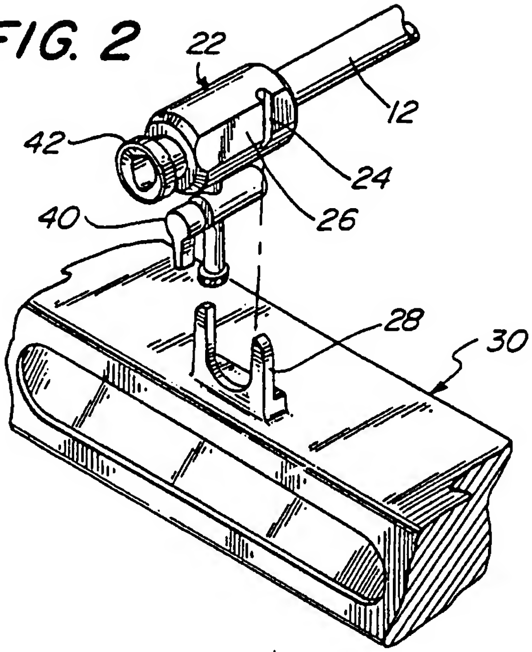


FIG. 3

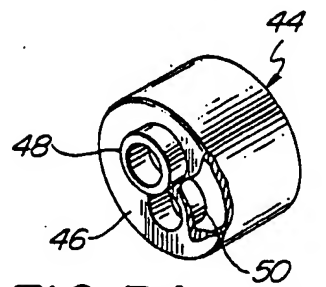


FIG. 3A

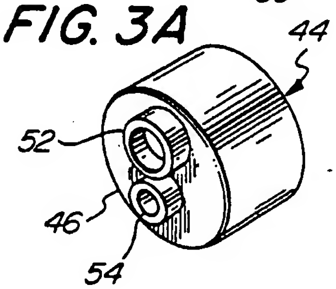


FIG. 4

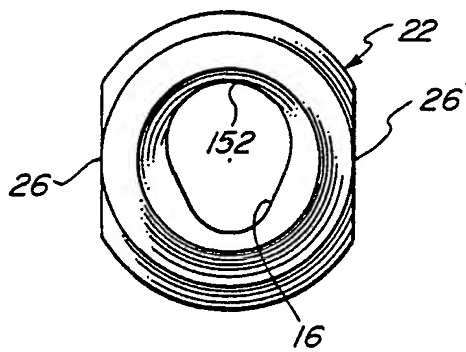


FIG. 5

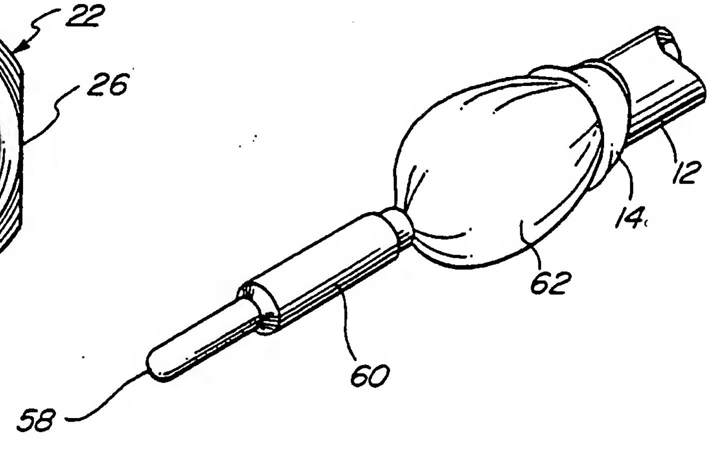
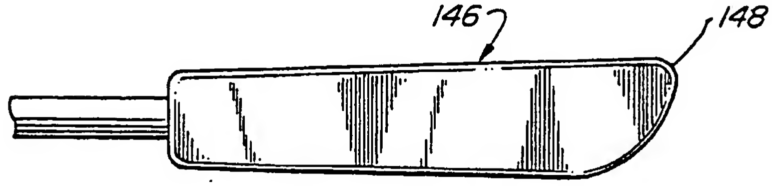


FIG. 6



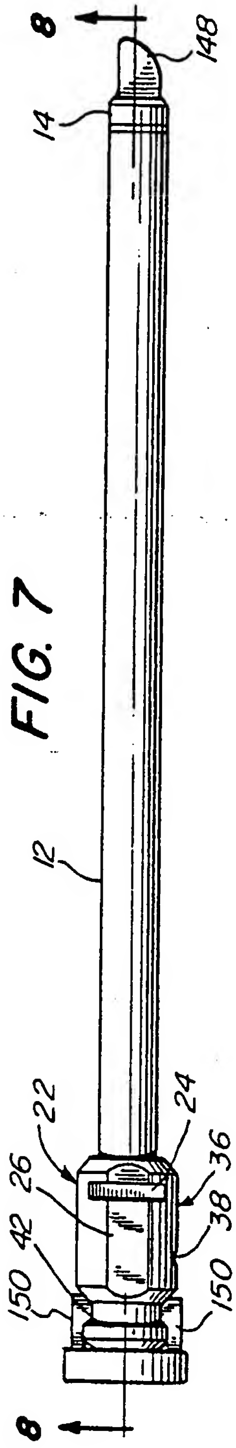


FIG. 7

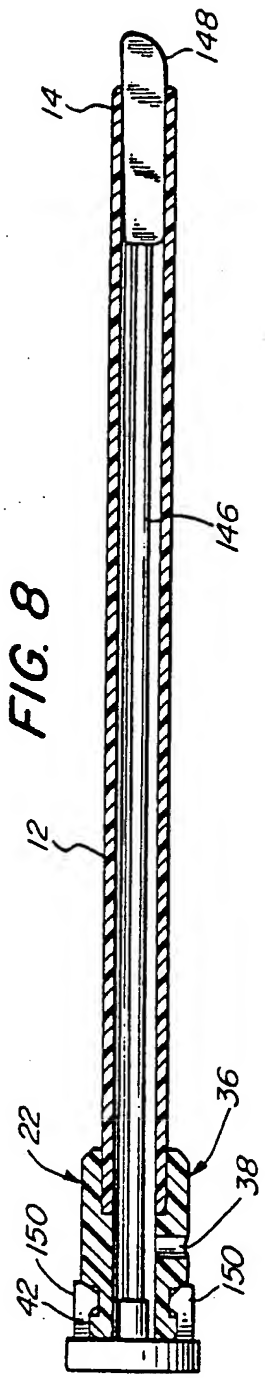


FIG. 8

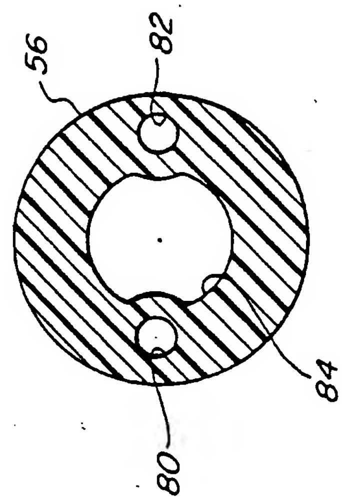


FIG. 10

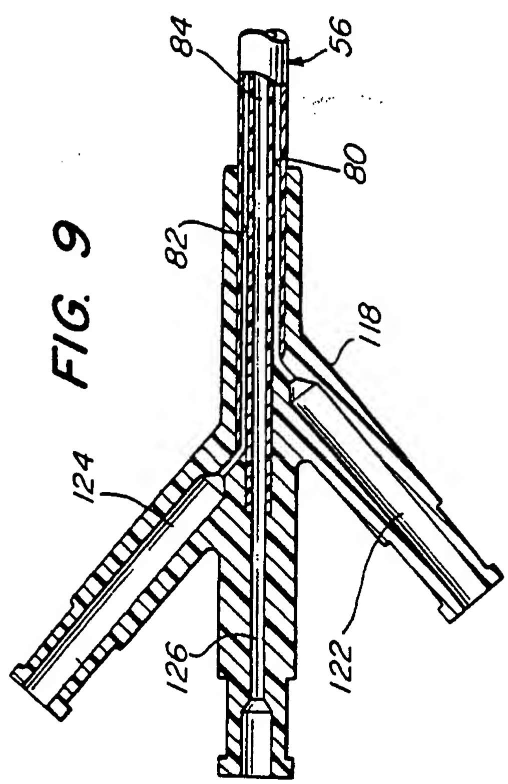


FIG. 9

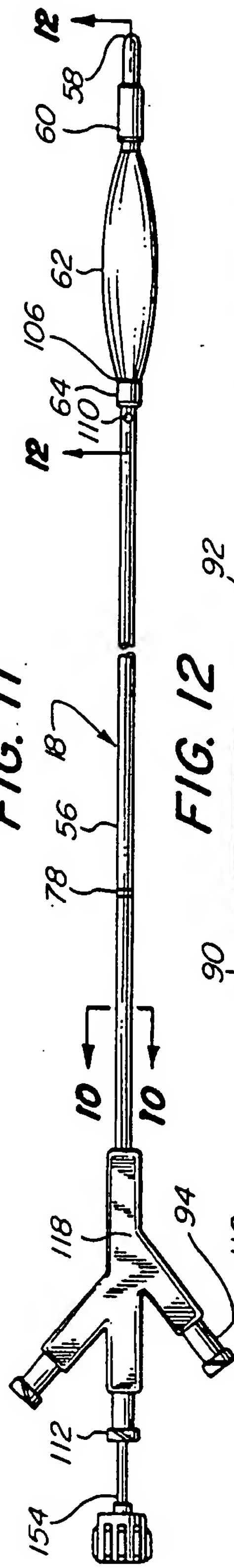


FIG. 11

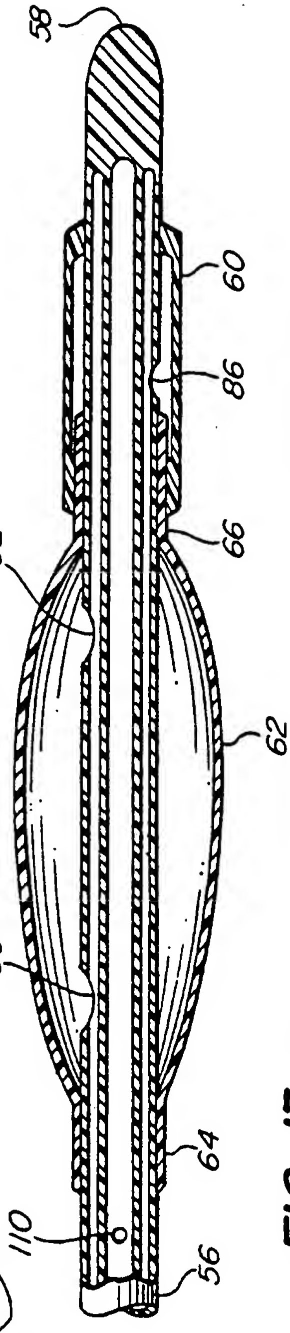


FIG. 12

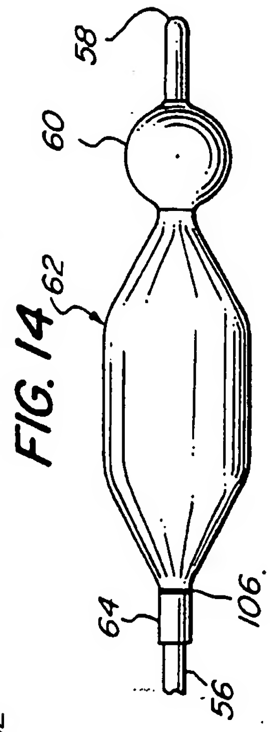


FIG. 14

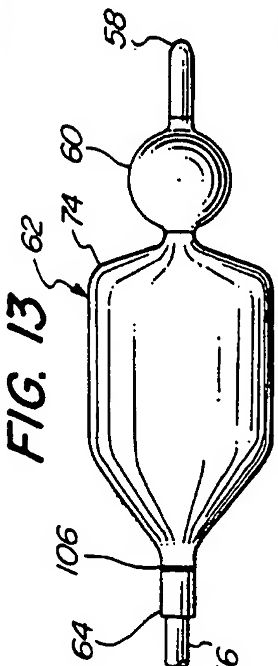


FIG. 13

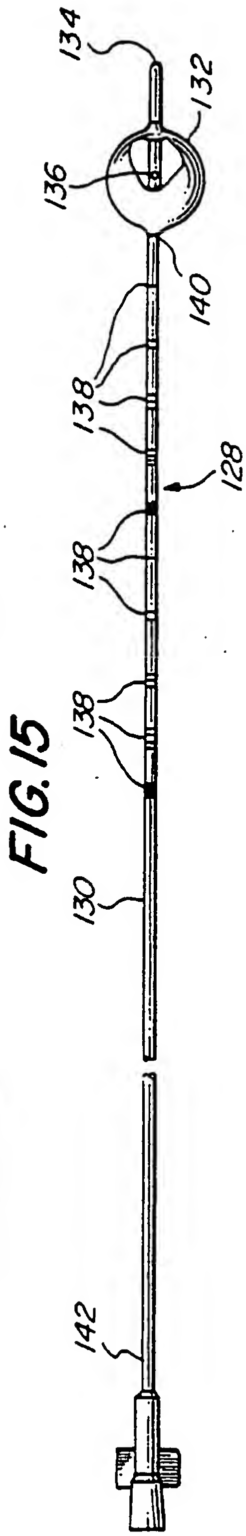


FIG. 15

FIG. 16

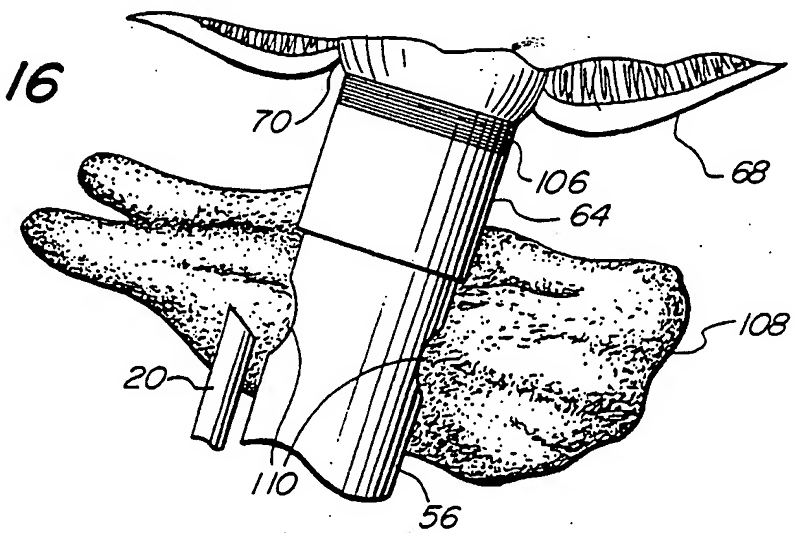
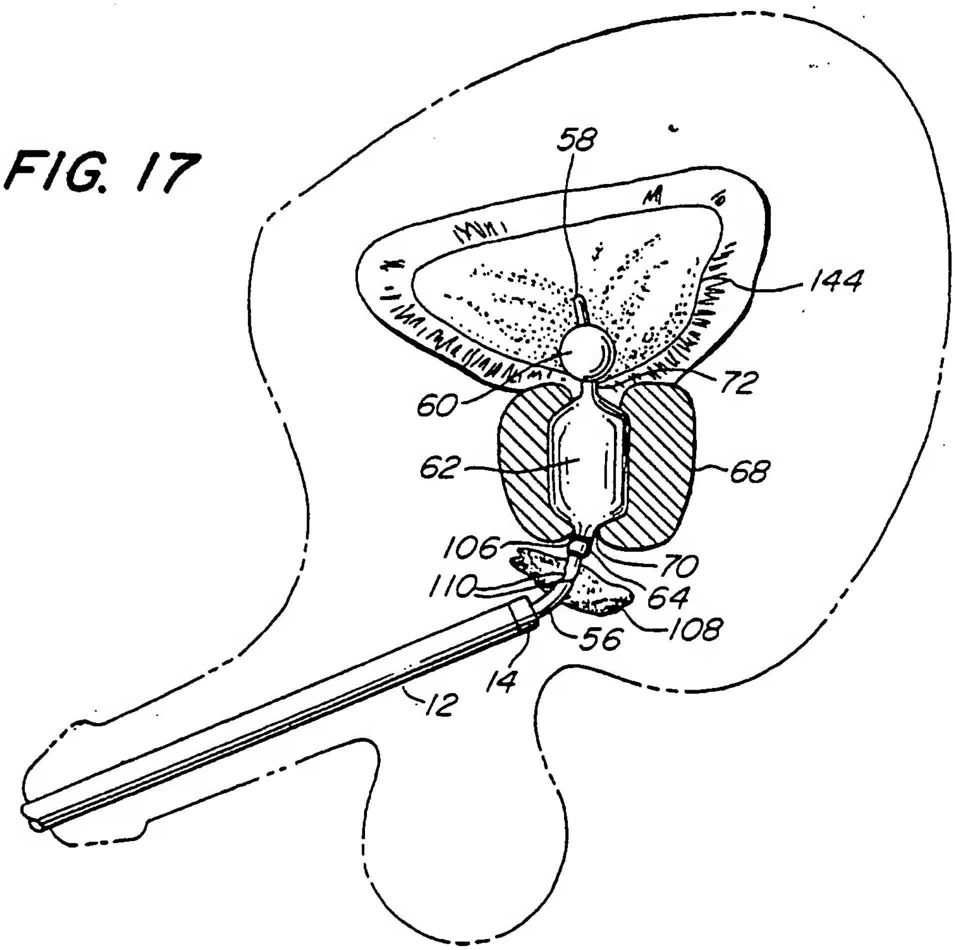

70
106
68
64
108
20
110
56

FIG. 17


58
144
72
60
62
68
106
70
110
64
108
56
14
12

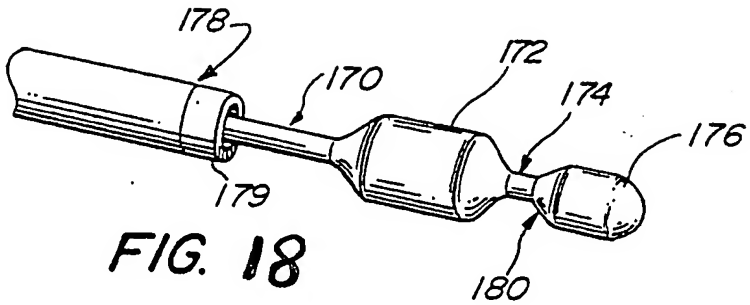


FIG. 18

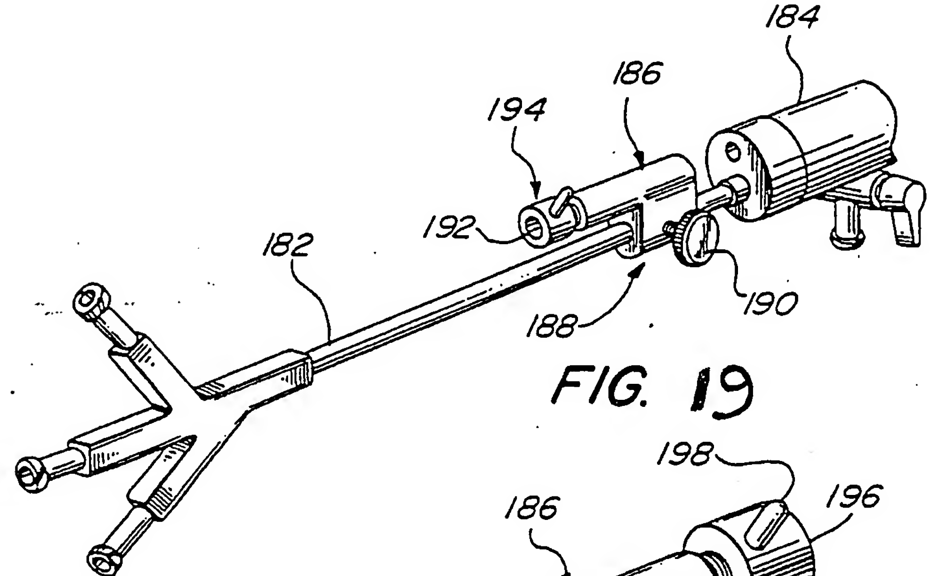


FIG. 19

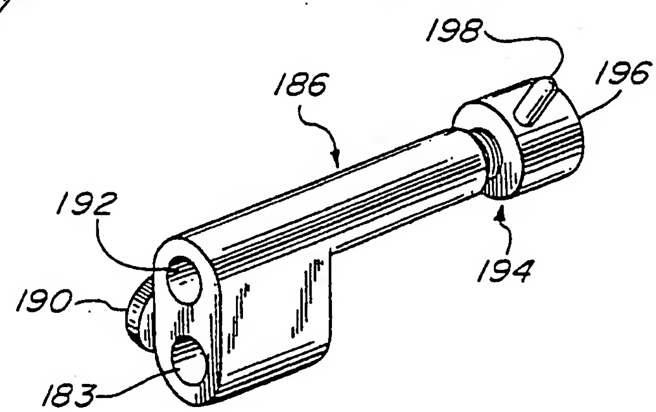


FIG. 20